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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,593	10/18/2001	Nana K. Ayisi	S&B-C161	5237

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,593	AYISI, NANA K.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20, 22, 31, 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2005 has been entered.

Claim Rejections - 35 USC § 112

The rejection claims 19-22 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting HIV viral replication in Vero cells and in Molt4 clone 8 cells with an extract of *O. gratissimum*, does not reasonably provide enablement for the *O. gratissimum* extract to inhibit HIV viral replication in a mammal or in any other cell line. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims **is maintained** for reasons of record.

Applicants' arguments and the Offices response are essentially the same of record. In response to Applicant's arguments, addressing the 35 USC § 112 rejection, that MPEP § 2164.02 does not require a rigorous or invariable exact correlation between the *in vitro* and *in vivo* model [citing Cross v. Iizuka, 224 USPQ 739 (Fed Cir. 1985)]. *In vitro* testing permits an investigator to establish the potency of a compound with respect to the particular pharmacological activity. In this case when treating HIV it is well established in the art that what is observed in the test tube does not necessarily pan out as treatment method in the patient, this was exemplified in the

case of Suramin discussed in the Office action of October 21, 2003, page 6. Even when using well-known cell lines, the information obtained from the cell lines does not necessarily provide any information regarding effect of the product *in vivo*. In the HIV art there are numerous examples in which laboratory strains of the virus are used for testing purposes in the lab and the products are effective in the *in vitro* setting. However, the effectiveness of the treatment tested *in vitro* has not panned out in the clinical setting where the virus in a patient is wild type virus and not the laboratory strain. The best example comes form the repeated efforts of trying to develop vaccine for the purpose of antibody production in the patient that would be effective at preventing viral entry in the cells *in vivo*. These antibodies, although effective against the laboratory strains, have not proven effective *in vivo* against wild type virus in the environment. The Office recognizes that FDA approval is not a prerequisite for finding utility (25 U.S.C. § 101) for purposes of patentability as pointed in In re Brana, 34 USPQ 2d 1436 (Fed. Cir. 1995). In this case utility was not questioned, the instant claims are rejected for failure to teach "how to use" the claimed invention in the unpredictable art of viral treatments.

Claim Rejections - 35 USC § 102

The rejection of claims 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by El-Said et al. (Planta Medicine, 1969) **is maintained** for reasons of record. The rejection is evidenced by the Merck Manual (Ed. Beers et al., Published by Merck Research Laboratories, Whitehouse Station, N.J. (1999) pp 1293-1296, 1303-1306, 1312-1323, 2320-2324 and 2341-2343).

The instant invention reads on treatment of a viral infection *in vivo* using an extract of *Ocimum gratissimum*. El-Said et al. disclose that use of an extract of *O. gratissimum* has been used in Nigerian herbal medicine for the treatment of fevers (see abstract). Fever is a symptom that is associated with viral or bacterial infections, this is evidenced by the Merck Manual. Therefore, the treatment of viral infection using an extract of *O. gratissimum* is anticipated by El-Said et al.

Applicants' arguments and the Offices response are essentially the same of record. In response to Applicant's arguments, addressing the 35 USC § 102 rejection, that a claim is anticipated only if each and every element is expressly or inherently described in the art reference (MPEP 2131) and a reference contains an enabling disclosure if the public was in possession of the claimed invention before the date of the invention (MPEP 2121.01). In this instant the prior art discloses the decoction (boiling leaves in water like tea) of *O. gratissimum* for the treatment of fever and diaphoretic and also as a stomachic laxative. Applicants' arguments are that the reference only discloses the preparation and testing of (a) an aqueous extract of the whole plant (b) the essential oil and (c) an aqueous solution of the essential oil for the ability to inhibit bacterial growth. The reference does not disclose anti-viral testing and/or a method of use *O. gratissimumfor* inhibiting the cytopathic effects of a virus infected cell. In response, where a method of the prior art is performed on either the same population or a subset of the same population as the claimed method using the same material and methodology, the prior art method inherently would achieve whatever desired outcome was discovered and claimed by applicant. In this instance Nigerian people used an infusion of the *O. gratissimum* for the purpose of treating fevers, fevers are a response by the body to combat bacterial or viral

infections. Though the Nigerian patient may not have appreciated the nuance that a compound found in the plant actually has a cytophatic effect on a virus in a test tube. The purpose of drinking the infusion of *O. gratissimum* by a patient is to help the patient get well. Applicants are asking that the Office grant them a patent where the Nigerian patient, who happens to be infected with a virus, would be infringing the instant claim by drinking tea made from *O. gratissimum*. The prior art discloses a method of administering an extract of *O. gratissimum* to a patient and the compounds responsible for inhibiting a virus would inherently be present in the extract. In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002). Applicants' arguments have not been found persuasive and the rejection is maintained for reasons of record.

Conclusion

No claims allowed.

This is an RCE of applicant's earlier Application No. 09/978593. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 4/15/05